

PU3126USW

diffraction which characterize a specific morphic form of a certain compound. It is well known in the art that the use of X-ray powder diffraction to determine whether a particular form of a compound is the same as a known morphic form of a compound requires the comparison of the X-ray powder diffraction spectra of the unknown form to that of the known form. Due to spectra being collected on different machines and under slightly different environmental conditions, one skilled in the art would expect that two spectra of the same morphic form taken at different times or on different machines would exhibit certain insignificant differences which would not be sufficient to indicate a different morphic form. The diffraction pattern of a particular polymorph is a finger-print for that polymorph in that the same pattern of peaks with consistent d-spacings, within experimental error, would be observed. Given the knowledge of those skilled in the art of the relatively imprecise nature of this comparison, Applicants respectfully submit that the use of "substantially" in the Instantly pending claims is as accurate as the subject permits and does not render the claims indefinite. Withdrawal of the instant rejection is therefore respectfully solicited.

Double Patenting Rejection Overcome

Claims 11 and 16-18 currently stand rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 7-10 of parent Patent No. 6,469,160. Applicants have filed concurrently herewith a terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) which obviates the instant rejection. Withdrawal of this rejection is therefor respectfully solicited.

Section 102(e) Rejection Overcome

Claims 11, 14 and 16-21 currently stand rejected under 35 U.S.C. §102(e), the Office Action stating that the claims are anticipated by U.S. Patent No. 6,077,832 to Chamberlain. More specifically, the Office Action refers to claims 20-23 and 26-28 of the '832 patent and states that "the particular crystal structure, mixture of crystal structures, or absence of crystal structure of the active Ingredient is deemed to be irrelevant to the pharmaceutical efficacy..." Applicants respectfully traverse this rejection.



PU3126USW

The instantly pending claims are directed toward specific crystalline forms of a compound, which compound is disclosed in the '832 patent. Neither the specific crystalline forms which are the subject of the instantly pending claims, nor their use in pharmaceutical compositions or methods are disclosed or suggested by the '832 patent.

Applicants have already stated on the record that the crystalline forms of the compound have the same pharmaceutical activity and uses as disclosed for the amorphous compound in the '832 patent. However, that does not support the conclusion that the claim elements reciting the specific crystalline form in the now pending claims are *irrelevant* for examination purposes.

Applicants respectfully remind the Examiner that to anticipate a claim, the reference must teach every element of the claim. MPEP 2131. "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913 (Fed. Cir. 1989). The '832 patent does not disclose every element of the instantly pending claims, nor does it disclose the identical invention. The instantly pending claims recite as an element specific crystalline forms of the compound that are neither disclosed nor suggested by the '832 patent. Accordingly, inasmuch as this claimed element is not taught in the cited reference, the instantly pending claims are not anticipated by the cited reference and withdrawal of this rejection is respectfully requested.

- 3 -

PU3126USW

Applicants respectfully submit that the instant application is in condition for allowance, which action is respectfully requested. The Examiner is invited to contact the undersigned at 483-8222, to discuss this case further if desired.

Respectfully submitted,



Lorie Ann Morgan
Attorney for Applicants
Registration No. 38,181

Date: 20 February, 2003
GlaxoSmithKline
Five Moore Drive, PO Box 13398
Research Triangle Park
North Carolina 27709
(919) 483-8222

- 4 -